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Guidance for the Reregistration of Pesticide Products Containing Propanil as the Active Ingredient

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Guidance for the Reregistration of Pesticide Products Containing Propanil as the Active Ingredient

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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

PROPANIL

(OPP NUMBER 028201)

AS THE ACTIVE INGREDIENT

CASE NUMBER 0226

CAS (DOCKET) NUMBER 709-98-8

DEC 23 1987

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C. 20460

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EPA Form 8570-27	Generic Data Exemption Statement

GLOSSARY OF TERMS AND ABBREVIATIONS

The following are terms used throughout Registration Standards and are defined here for the convenience of the reader.

ADI (Acceptable Daily Intake): An acceptable daily intake of pesticide residue based on a complete data base.

A/D Ratio: This ratio determines a level of concern regarding whether effects observed in embryos and fetuses from treated females are "primary" (due to direct compound-related effects) or "secondary" to maternal toxicity). Thus, the NOEL for maternal effects ("A" numerator) divided by the embryo/fetal NOEL ("D" for "developmental"), including frank terata (gross congenital defects), defines this concern. If A/D is less than "1", developmental toxicity of a substance may be ascribed to secondary effects of maternal toxicity; if greater than 2, the substance is considered a direct (primary) developmental toxicant. Scientific interpretation is required in the range, 1 to 2 (LELs may be used; or effects from other types of studies, e.g., reproduction).

ai: Active ingredient.

CAS: Chemical Abstract Service (number).

Core Classification: A general guide to the acceptability of data for the purpose of supporting registration (invalid, supplementary, minimum, or guideline).

Core Guideline: Studies which satisfy Agency data requirements.

Core Minimum: Studies which are acceptable to support registration of pesticide products but were not necessarily done according to Agency Guidelines.

Core Supplementary: Studies in this category are scientifically sound, thus the information may be useful. However, the studies were performed under conditions that deviated substantially from recommended protocols. Studies do not meet Guideline requirements and thus do not support registration of a product.

EEC (Estimated Environmental Concentration): Estimated pesticide concentration in the environment (terrestrial or aquatic ecosystem).

EP: End-Use Product.

EPA: The Environmental Protection Agency, also "the Agency."

FIFRA: The Federal Insecticide, Fungicide, and Rodenticide Act.

HDT: Highest dose tested.

Invalid: Studies which are deficient in some vital parameter or those studies which have been judged not to be scientifically sound or those studies whose reliability is seriously questioned.

LC_{50}: (Median lethal concentration): a statistically derived concentration of a substance that can be expected to cause death in 50 percent of test animals, expressed as weight or volume of test substance per volume of air or water or per weight of feed (e.g., mg/L or ppm).

LD_{50}: (Median lethal dose): a statistically derived single dose that can be expected to cause death in 50 percent of animals when administered by the route indicated, expressed as weight of substance per unit weight of test animal (e.g., mg/kg).

MOS (Margin of Safety): The calculation of a margin of safety involves division of an appropriate NOEL by a worker's estimated exposure. The result is a unitless figure which gives an indication of how close a worker's internal dose is in relation to the NOEL for laboratory animals.

MPI: Maximum Permissible Intake.

MRID (Master Record Identification (number)): EPA's system of tracking studies used in support of registrations.

MP: Manufacturing-use product.

NPDES: National Pollution Discharge Elimination System.

NOEL (No Observed Effect Level): The maximum dose used in a test which produces no observed adverse effects.

OPP: The Office of Pesticide Programs (EPA).

OES: Office of Endangered Species, U.S. Fish and Wildlife Service.

OM: Organic matter (used to describe soils).

ppm: Parts per million.

PADI (Provisional Acceptable Daily Intake): An acceptable daily intake of pesticide residue based on a limited data base.

PAI: Pure active ingredient.

TEP: Typical end-use product

Technical: Active ingredient as manufactured.

TMRC (Theoretical Maximum Residue Contribution): An estimate of dietary exposure obtained by multiplying residue tolerance levels for a given pesticide by the average daily per capita food consumption figure, then adding the exposure figures for each crop. TMRC is usually expressed in terms of mg/kg body weight per day.

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This document contains information regarding the registration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1] The scientific reviews may be obtained from the Information Services Section, Program Management and Support Division (TS-757C), EPA, 401 M St., SW, Washington, D.C. 20460.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

II. CHEMICAL COVERED BY THIS STANDARD

A. Description of Chemical

Common Name: Propanil

Chemical Name: 3',4'-dichloropropionanilide

Other Names: Surcopur, Supur, Propanex, Propanilo, Supernox, FW-734, Stam, Stampede, DPA, Herbax, Riselect, Erban, Chem Rice, Rogue, S-10165, Strel, Bay 30130

Chemical Abstracts Service (CAS) Number: 709-98-8

OPP (Shaughnessy) Number: 028201

Empirical Formula: $C_9H_9Cl_2NO$

Molecular Weight: 218.1

Description of Chemical Characteristics: Medium to dark grey solid with a mildly acrid odor. The chemical is readily soluble in ketones, alcohols and chlorinated solvents and has a melting point of 89 to to 92 °C. The density of propanil at 25°C is 1.25 g/ml. In strong acid or alkali, the chemical will hydrolyze to 3,4-dichloroaniline and propionic acid.

B. Use Profile

Type of Pesticide: Herbicide

Pests Controlled: Grass, broadleaf, and aquatic weeds

Registered Uses: Rice, spring barley, oats, and durum wheat

Predominant Uses: Rice (approximately 95% of manufactured pesticide)

Mode of Activity: Inhibition of a number of biochemical reactions, especially photosynthesis.

Formulation: Manufacturing-Use Products - 85%, 90%, and 96% ai (technical).

End-Use Products - 33%, 33.8%, 35%, and 35.9% ai (3 lb ai/gal) emulsifiable concentrate; 43.48%, 43.5%, 44.5%, 45%, and 45.4% ai (4 lb ai/gal) emulsifiable concentrate; 35% ai (3 lb ai/gal) soluble concentrate/liquid.

Methods of Application: Applied by conventional aerial or ground equipment as a postemergence application.

III. AGENCY ASSESSMENT

A. Summary

Based on the review of available data, the Agency has reached the conclusions set forth in this Standard. A summary of those conclusions follows. A more detailed discussion is contained in the remainder of this Chapter.

1. Acute toxicity cannot be assessed due to a lack of acceptable data. Two invalid acute oral studies indicate Toxicity Category III for propanil. The chronic toxicity data were developed from testing three technicals ranging in purity from 85 to 98% ai. Pending review of the impurity profiles of these technicals, certain studies may need to be repeated. A mouse oncogenicity study performed with 85.4 and 98% ai technicals reported findings of bilateral retinal degeneration and thyroiditis. Additional information is required on this study.

2. There are numerous data gaps under the environmental fate data requirements. Available data indicate that propanil is stable to hydrolysis at pH 7 and 9. Leaching studies indicate that the chemical is mobile to very mobile on sandy loam, silt loam, clay loam, clay, and sand soils. Pending the results of a mobility study with aged propanil and a field dissipation study, a ground water monitoring study may be required.

3. Effects to fish and wildlife cannot be fully assessed until all required studies are submitted and reviewed. There is a potential for risk to endangered aquatic species based on the use on rice. After formal consultation between the Agency and the U.S. Fish and Wildlife Service, labeling to protect endangered species may be required.

As a result of this review, the Agency has identified missing data necessary to evaluate the environmental and human risks associated with the use of propanil. Registrants must agree to develop these data in order to maintain registrations of products or register new products containing propanil. A summary of these data gaps appears in Table 1. Please note that this is only a summary and complete details can be obtained by referring to the tables in Appendix I.

The Agency is requiring a label restriction on drainage water from treated rice fields. Refer to Section D of this Chapter for specific language.

The Regulatory Position and Rationale section discusses the Agency's position regarding the regulation of propanil.

Table I. Summary of Data Gaps

Product Chemistry
- All product chemistry data

Residue Chemistry
- Metabolism studies (plants, livestock)
- Residue analytical method (plant and animal residues)
- Storage stability
- Residue studies

Toxicology
- Acute oral
- Acute dermal
- Acute inhalation
- Eye irritation
- Dermal irritation
- Dermal sensitization
- 21-day dermal
- Chronic toxicity (rodent and nonrodent)
- Oncogenicity (rat and mouse)
- General metabolism

Environmental Fate
- Hyrolysis
- Photodegradation (water and soil)
- Aerobic soil metabolism
- Anaerobic soil metabolism
- Anaerobic aquatic metabolism
- Aerobic aquatic metabolism
- Leaching, adsorption/desorption
- Soil dissipation
- Aquatic (sediment) dissipation
- Rotational crop (confined) accumulation
- Irrigated crops accumulation
- Fish accumulation

Fish and Wildlife
- Avian acute oral
- Avian subacute dietary (upland game bird and waterfowl)
- Freshwater fish toxicity [TEP] (coldwater fish and warmwater fish)
- Freshwater invertebrates acute toxicity [TEP]
- Estuarine and marine organisms acute toxicity
- Fish early life stage and aquatic invertebrate life cycle
- Fish life cycle

Plant Protection
- Seed germination/seedling emergence
- Vegetative vigor
- Aquatic plant growth

B. Toxicological Characteristics

The current toxicology data base for propanil is comprised of studies testing three different technicals. Rohm and Haas has two registered propanil technicals. One technical is labeled at 85% ai with a range of 85-88% (by weight) and was registered in 1972. The studies, discussed below, using this technical list the purity as 85.4%. The other technical propanil is of 97% purity* (although labeled at 96% ai) with an actual range of 95-99% ai (by weight). This technical was registered in April 1985. Studies using this technical list the purity as 98%. Additionally, a 97% purity technical was tested by Rohm and Haas, in the 1960's. This unregistered 97% technical may be chemically different from both registered technicals in use since that time. Depending upon the impurity profile of these technicals, it may be necessary to repeat certain studies such as reproduction (using 85% and/or 96% registered technicals), the teratology studies (with 96% registered technical), the mouse oncogenicity study (with 85% technical product) and possibly other studies. The registrant is required to address this issue in satisfactory detail.

1. Acute Toxicity

There are no acceptable data to assess acute toxicity. However, data from two invalid acute oral studies place propanil in Toxicity Category III.** An invalid primary skin irritation study indicates that propanil is a moderate skin irritant. Thus, due to a lack of valid data, the following studies are required: acute oral, acute dermal, acute inhalation, eye irritation, dermal irritation, and dermal sensitization.

2. Subchronic Toxicity

In a subchronic oral toxicity study, mice were dosed with 0, 25, 200, 1600 and 12,800 ppm technical propanil (98% ai). Ten male and ten female CD-1 mice were used per dose level. A No Observable Effect Level (NOEL) was established at 25 ppm and a Lowest Effect Level (LEL) was determined to be 200 ppm based on an increase in hepatocytic pleomorphism and hepatocellular multifocal necrosis. This study was classified Core Minimum and fulfills the requirements for a 90-day feeding study in a rodent species.

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* Based on available data.

** Toxicity Categories are based on the acute toxicity of the chemical (LD_{50} or LC_{50} values) and are used to determine the appropriate signal word and precautionary language for product labeling. Toxicity Category III requires the signal word CAUTION and precautions against swallowing, inhaling, or contact with the skin and eyes, along with appropriate first aid instructions.

There are no data available to assess subchronic dermal toxicity. A 21-day dermal study is required.

3. Chronic Toxicity

In a chronic feeding study, Wistar rats were dosed with 0, 100, 400 and 1600 ppm technical propanil (97% ai). Twenty-five male and twenty-five female rats were used per dose level. A NOEL was established at 100 ppm Lowest Dose Tested (LDT). A LEL was determined to be 400 ppm, based on increased relative spleen weight in females. The study was classified as Core-Supplementary because of inadequate histological examination of tissues in both sexes of rats, clinical chemistries were not performed and the limited number of rats used.

In a chronic feeding study, beagle dogs were dosed at 0, 100, 600 and 4000 ppm with technical propanil (97% ai). Two dogs per sex per dose were used. A NOEL was established at 600 ppm. A LEL was determined to be 4000 ppm based on decreased body weight, decreased food consumption and increased SGOT* and SAP** values. The study was classified as Core-Supplementary because of the inadequate number of dogs used and limited clinical chemistry and limited histopathology were performed.

Chronic feeding studies in rodents and in nonrodents are required.

4. Oncogenicity

An oncogenicity study was conducted in mice with technical propanil of two purities, 98% and 85.4% ai. Dose levels for the study were 0, 5, 30, and 180 ppm for the 98% ai technical and a second dose level of 180 ppm using the 85.4% ai technical. The oncogenic potential was negative at 180 ppm (HDT) for both technicals. There were no compound-related effects on survival, clinical observations, tissue masses, body weight, food consumption, hematology, or organ weights. Dose-related histologic findings were observed in the male liver as centrilobular hepatocytic enlargement beginning by week 15 and continuing for the 104-week study. The NOEL for this lesion was 30 ppm for the 98% ai technical. The LEL for this effect was 180 ppm (HDT) for both technicals. Bilateral retinal degeneration in male and female mice and thyroiditis in female mice were observed at 180 ppm (85.4% ai technical only), the only dose level tested for this technical. NOELs for these effects were not established. This study was classified as Core-Supplementary because the maximum tolerated dose (MTD) was not employed and NOELs for bilateral retinal degeneration and thyroiditis with the 85.4% ai technical were not established. Pending the results of any additionally submitted data on this study, the 2-year mouse study may need to be repeated with the 85.4% ai technical.

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* Serum glutamate oxalacetate transaminase

** Serum alkaline phosphatase

5. Teratogenicity

A teratology study in rats with 85.4% ai technical propanil tested the following doses: 0, 0.8, 4.0, 20, and 100 mg/kg. Results indicated a maternal toxicity NOEL of 20 mg/kg/day, a developmental toxicity NOEL of 20 mg/kg/day, and the teratogenic potential was negative. The study was classified as Core-Minimum and fulfills the teratology (rat) data requirement.

A teratology study in rabbits was performed with the 85.4% ai propanil technical. The following dosages were tested: 0, 4, 20, and 100 mg/kg/day. Results indicated a maternal toxicity NOEL of 20 mg/kg/day, a developmental toxicity NOEL of 20 mg/kg/day and teratogenic potential was negative. The study was classified as Core-Minimum and fulfills the teratology (rabbit) data requirement.

6. Reproduction

A 3-generation rat reproduction study using the 97% purity propanil technical tested dosages of 0, 100, 300, and 1000 ppm. There were no compound-related effects on fertility, gestation, viability, and lactation indicies, or sex ratios for each generation. Histopathologic examination of F3b pups did not reveal any compound-related lesions. The reproductive and systemic NOEL is 300 ppm. The study is acceptable and fulfills the 3-generation reproduction (rat) data requirement.

7. Mutagenicity

Acceptable studies have been submitted to satisfy the Agency's data requirements for gene mutations, chromosomal aberrations, and direct DNA damage. Propanil was not mutagenic in gene mutation assays, chromosomal aberration assays, and in all but one direct DNA damage assay.

8. Metabolism

In a rat metabolism study using only males, approximately 90 to 92 percent of the radioactivity was recovered in urine, feces, and cage washings within 2 days. Less than 1 percent was found in rat tissues. The predominant metabolite was 3',4'-dichloroaniline. The study was classified as Core-Supplementary because (1) individual data were not provided; (2) female rats were not studied; and (3) T 1/2 (half-life) was not determined. Another rat metabolism study is required to fulfill this data requirement.

C. Other Science Findings

1. Environmental Fate

Available data are insufficient to fully assess the environmental fate of propanil. Data Table A lists the required environmental fate studies. Available data indicate that propanil is stable to hydrolysis at pH 7 and 9. Leaching studies (adsorption/desorption) indicate that the chemical is mobile to very mobile on sandy loam, silt loam, clay loam, clay, and sand soils. Mobility appears to be related to organic content of the soil; the lower the organic content, the more mobile propanil is in the soil. Pending the results of anaerobic/aerobic soil metabolism, aquatic metabolism, mobility and field dissipation studies, a groundwater monitoring study may be required.

2. Exposure

Since the currently available data do not indicate a basis for concern and based on current use patterns, the Agency is deferring any requirements for exposure data. Should the toxicity studies required in this Standard indicate a concern for human exposure, appropriate exposure data will be required.

3. Ecological Effects

a. Terrestrial Organisms

Available data indicate that propanil, on a subacute dietary basis, is slightly to practically nontoxic to birds. Eight-day dietary studies on bobwhite quail and mallard duck reported LC_{50} values of 1924 ppm and greater than 5000 ppm, respectively. Although these studies provide enough information to characterize propanil, deficiencies in testing procedures prevent fulfillment of the avian subacute dietary data requirement. Thus, avian dietary studies on an upland game bird and waterfowl are required. No data are available to assess the acute oral toxicity of propanil to birds. An avian oral study is required.

An avian reproduction study is not required at this time since insufficient data are presently available to determine if this study will be required.

There is sufficient information to characterize propanil as relatively nontoxic to honey bees, when bees are exposed to direct treatment.

b. Aquatic Organisms

There are sufficient data available to characterize technical propanil as moderately to very highly toxic to freshwater fish. Reported 96-hour LC_{50} values for bluegill range from less than 3.7 to 5.36 ppm and for rainbow trout it is 2.3 ppm. The data requirements for freshwater fish LC_{50} studies (warmwater and coldwater fish species), using technical propanil, are satisfied.

Available data from acute fish toxicity studies using a typical end-use product (TEP) indicate the TEP as slightly to moderately toxic to fish. A bluegill study, testing a 45% ai TEP, reported a LC_{50} value of 16.49 ppm. An LC_{50} value of 6.9 ppm was reported when rainbow trout were tested with a 36.5% ai TEP. The information provided from these studies is sufficient to characterize the TEP. However, in both studies, only a 48-hour LC_{50} was determined; not the required 96-hour LC_{50}. Thus, the data requirement for the TEP has not been satisfied. Testing of the TEP is required since the application of propanil on rice, as allowed by the label, of 6 lb ai/A would result in an aquatic estimated environmental concentration (EEC) of 4.4 ppm (as calculated by the Agency), which exceeds the technical propanil LC_{50} values for finfish.

A fish early life stage study and aquatic invertebrate life cycle study are required since the use of propanil to control weeds in rice is expected to result in water, containing the chemical, being transported from the site of application.

Results of a 48-hour study using *Daphnia magna* and testing technical propanil indicate a LC_{50} value of 6.7 ppm. This study characterizes technical propanil as slightly to moderately toxic to aquatic invertebrates. The freshwater invertebrate acute LC_{50} data requirement has been satisfied.

An acute LC_{50} freshwater invertebrate study using a TEP is required since the end use product is introduced directly into an aquatic environment when used as directed and the EEC of 4.4 ppm in 6 inches of water is very near the LC_{50} for *Daphnia magna*.

There is sufficient information to characterize propanil as slightly to moderately toxic to estuarine and marine organisms. However, the available studies do not satisfy the acute LC_{50} data requirement, since insufficient data were submitted and an unacceptable test species (mud crab) was used in one of the studies. The acute LC_{50} estuarine and marine organism data requirement must be fulfilled.

c. Plant Protection

Plant protection testing is required for propanil in order to assess the potential hazard to both terrestrial and aquatic nontarget plants.

d. Endangered Species

There are no endangered plant species associated with the registered uses of propanil. There is potential for endangered avian and aquatic species to be adversely affected by applications of propanil. However, no avian or aquatic endangered species have been identified in the small grain cluster.* The rice cluster is currently being developed by the Agency, and the Agency believes that the fat pocketbook pearly mussel (*Potamilus capax*) could be at jeopardy. Endangered species labeling may be required for propanil upon completion of a formal consultation with the U.S. Fish and Wildlife Service if their review concludes that the use of propanil on rice causes jeopardy to endangered species.

4. Product Chemistry

a. Potential Contamination with Halogenated Dibenzo-p-dioxins or Dibenzofurans

The Agency finds that chemicals such as propanil that have had a halogenated cyclic moiety within their structures have the potential of becoming contaminated with halogenated dibenzo-p-dioxins or dibenzofurans under certain conditions of manufacture. Information on the manufacture of propanil is needed in order to determine whether conditions favoring the formation of halogenated dibenzo-p-dioxins or dibenzofurans occur during propanil manufacture. Submission of product identity and composition and manufacturing process data on all propanil products was required in a data call-in notice dated June 9, 1987. The data were required by January, 1988. If the manufacturing process data show that halogenated dibenzo-p-dioxins are likely to be present in propanil products, the Agency may require analytic data to characterize or quantify any such contaminants.

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* Under the cluster program, the Agency assesses the individual risk to endangered species from all chemicals within the same use pattern (or "cluster") together.

b. Composition of Technical Grade Products

The amount of propanil in each of four technical grade propanil products ranges from 85% in one Rohm and Haas product to 97% in another technical grade product made by the same company. A Cedar Chemical Corp. technical contains 90% propanil. An unregistered technical made by Agrotan S.A. contains 95% propanil. Because the proportion of propanil varies so widely among the four technical grade products, the Agency is concerned that these products may be quite dissimilar in composition with respect to impurities and contaminants. Accordingly, the Agency is requiring submission of product chemistry data on each technical grade propanil product. If the product chemistry data show that the compositions of the technical grade propanil products are not comparable, it may be necessary to require complete toxicological testing of each technical grade propanil product.

D. Tolerance Reassessment

Tolerances have been established for residues of propanil in or on a variety of raw agricultural commodities (RACs) (40 CFR 180.222). EPA has evaluated the residue and toxicology data supporting tolerances, and has addressed the following regulatory issues:

- Whether the current tolerances are sufficient to cover the actual residues resulting from use (including uses registered under FIFRA section 24(c) and intrastate uses and methods of applications).

- Whether group tolerances could be established in accordance with 40 CFR 180.34(f).

- Whether, in the absence of tolerances, restrictions on use, grazing, or feeding of treated commodities are necessary.

- Whether the tolerances are expressed accurately and in current terminology.

The regulatory results of the Agency's reviews are set out in Section IV.A., Regulatory Positions and Rationales.

1. Residue Data

The residue data reviewed in support of these tolerances include the following:

a. Data on the nature of the residues in both plants and animals, including identification of major metabolites and degradates of propanil. The metabolite 3,4-dichloroaniline is common to plant and animal systems. Since its analog 4-chloroaniline is an oncogen, particular attention will be given to 3,4-dichloroaniline when quantifying residues in food crops and livestock.

b. Radiolabeled studies on the uptake, translocation, and metabolism of propanil in plants. Available data, although inadequate, indicate that residues of propanil are taken up systemically from soil into rice straw and grain.

c. Radiolabeled studies on the metabolism of propanil in poultry and ruminants. The limited data available indicate that ^{14}C-residues of propanil will occur in tissues of ruminants and poultry following ingestion of feeds containing [^{14}C] propanil.

d. Analytical methodology for determining the levels of residues of propanil in plants and animals. Since the nature of the residue in plants and animals has not been adequately described, the adequacy of available analytical methods cannot be ascertained. The current preferred enforcement method is a gas chromatographic procedure (Method I in the Pesticide Analytical Manual, Vol. II, Pesticide Reg. Section 180.274). This method has undergone a successful method tryout on milk. A colorimetric method has also been developed (Method II in the PAM, Vol. II). This method has, in the past, been considered acceptable for data collection but not for enforcement due to its inability to differentiate between substituted anilines.

e. Storage stability data. Available data indicate that residues of propanil in frozen rice grain will be stable for up to 525 days and in rice straw kept at room temperature for up to 235 days.

f. Data on the magnitude and levels of residues of propanil in individual RACs, animal products, and processed food and feed items. Data are insufficient to assess the established tolerances for residues in meat, milk, eggs, and rice grain. Furthermore, if the required plant metabolism and analytical method validation data indicate that all residues of concern were not determined in the currently available studies for the processed products of rice, rice straw, or the grain and straw of barley, oats and wheat, additional data may be required for these commodities as well. A wheat processing study is needed to determine whether food/feed additive tolerances are needed for the processed products of barley, oats and wheat.

2. Toxicology Data

The 2-year rat feeding study was used in determining the provisional acceptable daily intake (PADI). The NOEL for the rat study was 5 mg/kg/day (100 ppm). An uncertainty factor of 1000 was used to account for the inter- and intraspecies differences and the toxicology data gaps. The PADI was obtained by dividing the NOEL by the uncertainty factor of 1000. The resultant PADI was 0.005 mg/kg/day. The theoretical maximum residue contribution (TMRC) of propanil in the daily diet of the U.S. population average is 0.0015 mg/kg/day, based on the existing tolerances, with 29% of the PADI being utilized.

3. Tolerances Issued

The following tolerances have been established for residues of propanil:

Commodity	Tolerance (ppm)
Barley, grain	0.2
Barley, straw	0.75
Cattle, fat	0.1 (N)*
Cattle, mbyp**	0.1 (N)
Cattle, meat	0.1 (N)
Eggs	0.05 (N)
Goats, fat	0.1 (N)
Goats, mbyp	0.1 (N)
Goats, meat	0.1 (N)
Hogs, fat	0.1 (N)
Hogs, mbyp	0.1 (N)
Hogs, meat	0.1 (N)
Horses, fat	0.1 (N)
Horses, mbyp	0.1 (N)
Horses, meat	0.1 (N)
Milk	0.05 (N)
Oats, grain	0.2
Oats, straw	0.75
Poultry, fat	0.1 (N)
Poultry, mbyp	0.1 (N)
Poultry, meat	0.1 (N)
Rice	2
Rice, straw	75 (N)

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* Negligible residues

** Meat byproducts

Commodity	Tolerance (ppm)
Sheep, fat	0.1 (N)
Sheep, mbyp	0.1 (N)
Sheep, meat	0.1 (N)
Wheat, grain	0.2
Wheat, straw	0.75

A feed additive tolerance of 10 ppm is established for propanil in or on rice bran, rice hulls, rich polishings and other milling fractions resulting from application of the herbicide to the growing RAC rice.

Canadian Tolerances

Commodity	Tolerance (ppm)
Barley	0.1 ppm (N)
Oats	0.1 ppm (N)
Wheat	0.1 ppm (N)

Mexican Tolerances

Commodity	Tolerance (ppm)
Rice	2 ppm
Rice, straw	75 ppm

There are no Codex Alimentarius maximum residue limits.

IV. REGULATORY POSITION AND RATIONALE

A. Regulatory Position and Rationale

Based on review and evaluation of all available data and other relevant information on propanil, the Agency has made the following determinations:

1. The Agency is not initiating a Special Review of propanil at this time.

Rationale: Since available data are limited, the Agency is not yet able to make a determination as to whether any of the criteria specified in 40 CFR 154.7 have been met or exceeded.

2. The Agency will not establish significant* new food uses at this time.

Rationale: Because of extensive data gaps in the areas of residues and chronic toxicity, the Agency cannot assess existing uses. When additional data are evaluated, the Agency will determine whether significant new food uses may be established.

3. The Agency is not imposing any reentry statements nor is it requesting that reentry data be submitted.

Rationale: No toxicological concerns which would indicate the need for reentry statements or reentry data have been identified at this time. This conclusion is subject to change based on evaluation of required toxicological data.

4. Tolerances for residues in catfish and crayfish must be proposed and supporting data submitted. In lieu of proposing tolerances for catfish and crayfish, the following label restrictions may be implemented:

"Do not drain water from treated fields into areas where catfish farming is practiced." and

"Do not apply to fields where commercial crayfish farming is practiced and do not drain water from treated fields into areas where crayfish farming is practiced."

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* Significant new use is defined in 44 FR 27934, May 11, 1979. In the case of a new food or feed use, the Agency will consider as significant an increase in Theoretical Maximum Residue Contribution of greater than 1 percent.

Rationale: Available data on residues in catfish and crayfish indicate some likelihood of measurable residues occurring in edible portions of these fish/crustaceans. The registrant(s) must inform the Agency within 90 days which option is selected.

5. The Agency has determined that label restrictions on drainage water must be implemented. Refer to Section D of this Chapter for the specific language.

Rationale: Available data indicate that residues may occur up to 15 ppb in rice flood water drained 3 weeks prior to harvest from fields treated 56 days prior to harvest. Thus, application to rice may result in residues in catfish, crayfish, irrigation, and potable water due to drainage of rice flood water into catfish/crayfish farming waters, irrigation systems and potable water intakes.

6. The registrant must propose a resolution to the apparent conflict between feed additive tolerances for residues in rice bran and expected residues, if available rice processing studies are determined to be adequate.

Rationale: Available data indicate that the current 5X concentration factor may be inappropriate and that concentration may be as high as 13X in bran processed from rice grain. However, the Agency cannot determine if these data are adequate until plant metabolism and analytical method validation data are submitted and reviewed. If these data are determined to be adequate, the registrant must propose a means to resolve the difference between the existing feed additive tolerance and the expected residues. This may include, but is not limited to, proposed modifications to application rates or methodologies, or proposed tolerance revisions.

7. The registrant must propose a resolution to the apparent conflict between tolerances for residues in or on barley, oats and wheat straw, and expected residues, if available straw data for these commodities are determined to be adequate.

Rationale: Available data indicate that residues on these commodities may be as high as 1.5 ppm (existing tolerance is 0.75 ppm). However, the Agency cannot determine if the available data are adequate until plant metabolism and analytical method validation data are submitted and reviewed. If these data are determined to be adequate, the registrant must propose a means to resolve the difference between the existing tolerance and the expected residues. This may include, but is not limited to, proposed modifications to application rates or methodologies, or proposed tolerance revisions.

8. The Agency has determined that the following revision in the tolerances listed in 40 CFR 180.274 is necessary and will initiate actions to effect these changes.

° The designation "(N)" for negligible residues will be deleted from the entries for milk, eggs, meat, fat, and meat byproducts of cattle, goats, hogs, horses, sheep, and poultry, and rice straw.

Rationale: The Agency does not accept the concept of negligible residues therefore, the designation "(N)" will no longer be used.

9. The Agency is requiring complete product chemistry data on each technical grade propanil product.

Rationale: Available data on product identity and composition of each of the four technical grade products show that the percentage of active ingredient in the technical product varies widely among the four products. Accordingly, the Agency is concerned that differences in composition among the four products may be so great that toxicological data developed on one technical may not support products derived from the other technical grade propanil products. Review of product chemistry data on each technical will enable the Agency to determine whether this concern is founded, and if so, what additional data will be required.

10. The Agency has identified certain data that will receive immediate review when submitted.

Rationale: Certain data are essential to the Agency's assessment of this pesticide and its uses and/or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive priority review as soon as they are received by the Agency:

§158.120 Product Chemistry

61-1, 61-2 and 61-3; Product Identity, Manufacturing Process and Formation of Impurities

§158.125 Residue Chemistry

171-4 Metabolism Studies

§158.130 Environmental Fate

163-1, 164-1, 164-2; Leaching and Adsorption/Desorption, Soil Field Dissipation and Aquatic Sediment Field Dissipation

11. While data gaps are being filled, currently registered MPs and EPs containing propanil as the sole active ingredient may be sold, distributed, formulated, and used, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency does not normally cancel or withhold registration simply because data are missing or are inadequate [see FIFRA section 3(c)(2)(B) and 3(c)(7)].

Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory changes are necessary.

B. Criteria for Registration

To be registered or reregistered under this Standard, products must contain propanil as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. Acceptable Ranges and Limits

1. Product Composition Standard

To be registered or reregistered under this Standard, MPs must contain propanil as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1 percent.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and MPs containing propanil provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products must be labeled for formulation into end-use products for registered uses, as listed in the EPA Compendium of Acceptable Uses, Appendix III.

D. Labeling

All propanil products must bear appropriate labeling as specified in 40 CFR 162.10. Appendix II contains information on label requirements.

No pesticide product containing propanil may be released for shipment by the registrant after February 1, 1989, unless the product bears an amended label which complies with the requirements of this Standard.

No pesticide product containing propanil may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered to be delivered by any person after February 1, 1990, unless the product bears an amended label which complies with the requirements of this Standard.

In addition to the above, in order to remain in compliance with FIFRA, the following information must appear on the labeling:

1. Ingredient Statement

The ingredient statement for MPs must list the active ingredient as:

"3',4'-dichloropropionanilide"

2. Use Pattern Statements

All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify sites, which are listed in Use Patterns, Section C.3. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in Table A for that use pattern.

3. Precautionary Statements

The following statement must appear on manufacturing-use products under the heading "Environmental Hazards":

> "This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."

The following statement must appear on end-use products labeled for aquatic uses under the heading "Environmental Hazards":

> "This pesticide is toxic to fish. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water except as specified on this label. Do not contaminate water by cleaning of equipment or disposal of wastes."

All end-use products labeled for rice must contain the following label statement:

> "Water drained from treated rice fields must not be used to irrigate other crops or released within 1/2 mile upstream of a potable water intake in flowing water (i.e., river, stream, etc.) or within 1/2 mile of a potable water intake in a standing body of water such as a lake, pond or reservoir."

The following statement must appear on end-use products labeled for nonaquatic uses under the heading "Environmental Hazards":

> "This pesticide is toxic to fish. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water by cleaning of equipment or disposal of wastes."

The following statements must appear on end-use products labeled for aquatic uses, if the registrant of the product chooses not to conduct tests and propose tolerances for catfish and crayfish:

> "Do not drain water from treated fields into areas where catfish farming is practiced."
>
> "Do not apply to fields where commercial crayfish farming is practiced and do not drain water from treated fields into areas where crayfish farming is practiced."

4. Disposal Statements

The labels of all products must bear the appropriate pesticide and container disposal statements (See Appendix II).

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

1. The data requirements listed in Table A.

2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

2. If eligible for the formulator's exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use products in Section IV.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide

EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other

registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Testing Protocols, Standards for Conducting Acceptable Tests, Guidance on Evaluating and Reporting Data.

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing.

As noted herein, these EPA Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

F. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

G. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made by the 90-day deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.E.

EPA will view failure to request an extension before the data submission response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

H. PR Notice 86-5 and Any Other Requirements Referenced or Included Within this Notice.

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986).

I. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

   a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

   b. Confidential Statement of Formula (EPA Form 8570-4).

   c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

   d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months of receipt of this document, you must submit to the Product Manager:

Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

3. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

Within 9 months from the receipt of this document, you must submit to the Product Manager:

Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

E. Intrastate Products containing the subject pesticide either as sole active ingredient or in combination with other active ingredients.

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

F. Addresses

The required information must be submitted to the following address:

Robert J. Taylor, PM(25)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Assurance Division
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

GUIDE TO TABLES

Tables A, and B contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

> YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.
>
> PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.
>
> NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

SPECIAL NOTE REGARDING THE DATA TABLES

Testing of each technical grade propanil product is required under the Data Tables wherever "TGAI" is listed as the test substance, unless the registrant can demonstrate to the Agency that the compositions of the various technical propanil products are comparable.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPANIL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?[1]/	Bibliographic Citation[1]/	Must Additional Data Be Submitted?	Timeframe for Submission
§158.120 Product Chemistry						
Product Identity						
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	No	N/A	Yes[2]/[3]/	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	No	N/A	Yes[2]/[4]/	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	All	No	N/A	Yes[5]/	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	No	N/A	Yes[6]/	6 Months
63-3 - Physical State	TGAI	All	No	N/A	Yes[6]/	6 Months
63-4 - Odor	TGAI	All	No	N/A	Yes[6]/	6 Months
63-5 - Melting Point	TGAI	All	No	N/A	Yes[6]/[7]/	6 Months
63-6 - Boiling Point	TGAI	All	No	N/A	Yes[6]/[8]/	6 Months
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	No	N/A	Yes[6]/	6 Months
63-8 - Solubility	TGAI or PAI	All	No	N/A	Yes[6]/	6 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPANIL (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation1/	Must Additional Data Be Submitted?	Timeframe for Submission
§158.120 Product Chemistry						
Physical and Chemical Characteristics (cont'd)						
63-9 - Vapor Pressure	TGAI or PAI	All	No	N/A	Yes6/	6 Months
63-10 - Dissociation Constant	TGAI or PAI	All	No	N/A	Yes6/	6 Months
63-11 - Octanol/Water Partition Coefficient	PAI	All	No	N/A	Yes6/9/	6 Months
63-12 - pH	TGAI	All	No	N/A	Yes6/10/	6 Months
63-13 - Storage Stability	TGAI	All	No	N/A	Yes6/	15 Months
Other Requirements						
64-1 - Submittal of Samples	TGAI, PAI	All	N/A	N/A	No	

1/Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introducted and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/Required for all technical grade propanil products (registered and unregistered).

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPANIL (cont'd)

§158.120 Product Chemistry

Footnotes (cont'd)

3/Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions including specification of the acceptable conditions of temperature, pressure and pH, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

4/A detailed discussion of all impurities that are or may be present at $\geq$ 0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted. The discussion must include all details regarding possible formation of dibenzo-p-dioxins and dibenzofurans.

5/Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

6/Physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, K_{ow}, pH, and stability) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D must be submitted.

7/Data needed if the technical chemical is a solid at room temperature.

8/Data needed if the technical chemical is a liquid at room temperature.

9/Required if the technical chemical is organic and nonpolar.

10/Required if the test substance is dispersible with water.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPANIL

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry					
171-2 - Chemical Identity	TGAI	No		Yes	1/
171-3 - Directions for Use	--	Yes	Product Label	No	
171-4 - Nature of Residue (Metabolism)					
- Plants	PAIRA	Partially	00035588,00035589, 00035684,00036100, 00052347,00052348, 00052349,00052350	Yes[2]	18 Months
- Livestock	PAIRA	Partially	00035697,00035698, 00035699,00035905, 00067394	Yes[3]	18 Months
171-4 - Residue Analytical Method					
- Plant Residues	TGAI & Metabolites	Partially	00035587,00055547, 00067394,00076113, 00111367,00111388	Yes[2]	18 Months
- Animal Residues	TGAI & Metabolites	Partially	00055547,00067394, 00111367	Yes[3][11]	18 Months
171-4 - Storage Stability	PAI or TEP & Metabolites	Partially	00035683	Yes[4][5]	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPANIL (cont'd)

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry					
171-4 - Magnitude of the Residue - Residue Studies for Each Food Use					
- Crop Group #1 (Cereal Grains)		N/A		No[6]/	
- Forage, Fodder, and Straw of Cereal Grain Group		N/A		No[6]/	
- Barley, Oats, and Wheat	TEP	Partially	00055546,00078930, 00111370,00111373	Yes[7]/[15]/	18 Months
- Processed Products of Barley, Oats, and Wheat	EP	No		Yes[8]/[15]/	24 Months
- Rice	TEP	Partially	00035687,00035688	Yes[9]/[15]/	18 Months
- Processed Products of Rice	EP	Partially	00035576,00035687, 00035688,00052347	Yes[10]/[15]/	24 Months
- Potable & Irrigation Water	EP	Partially	00035688	Yes	15 Months
- Crayfish	PAIRA & EP	Partially	00035692,00111394	Yes[11]/[12]/	18 Months
- Catfish	EP	Partially	00111394	Yes[13]/	18 Months
- Meat, Milk, Poultry, & Eggs	TGAI or Plant Metabolites	Partially	00035694,00035695	Yes[14]/	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPANIL (cont'd)

§158.125 Residue Chemistry

Footnotes

1/Refer to Product Chemistry Data Requirement tables.

2/Metabolism studies must be submitted in which rice and wheat are treated foliarly and via the soil (in separate tests) with [^{14}C-ring]propanil at a rate sufficiently high to permit complete characterization of ^{14}C-residues in straw and mature grain. Plants should be grown under environmental conditions that approximate actual field conditions (i.e., rice should be flooded within 24 hours after treatment). Wheat should be treated at the four- or five-leaf stage and rice at the mid-tillering stage. Plants should be harvested at several intervals thereafter (every 2 weeks) and at maturity. At maturity, straw and grain must be analyzed separately. ^{14}C-Balance data must be presented for each sample analyzed. Conjugated or bound ^{14}C-residues must be characterized. Particular attention should be given to quantification of 3,4-dichloroaniline. Representative samples from these studies must be analyzed using all current and proposed enforcement procedures (including FDA multiresidue methods) to ascertain that the methods are capable of accurately quantifying all residues of toxicological concern.

3/Metabolism studies must be submitted in which ruminants and poultry are fed [^{14}C-ring]propanil for at least 3 consecutive days at a rate sufficient to permit complete characterization of ^{14}C-residues in muscle, fat, kidney, liver, milk, and eggs. Animals must be sacrificed within 24 hours of the final dose. Milk and eggs must be collected twice daily. ^{14}C-Balance data must be presented for each sample analyzed. Conjugated or bound ^{14}C-residues must be characterized. Particular attention should be given to quantification of 3,4-dichloroaniline Representative samples from these studies must be analyzed using all current and proposed enforcement procedures (including FDA multiresidue methods) to ascertain that the methods are capable of accurately quantifying all residues of toxicological concern. If metabolism of propanil in ruminants or poultry differs significantly from that in rats, a swine metabolism study may be required also.

4/All residue data required in this Standard must be accompanied by (i) sample storage information (storage conditions and length of time in storage) and (ii) data depicting the stability of propanil residues of concern in similar samples stored for the time intervals and under the conditions specified. If Method II in Pesticide Analytical Manual (PAM) Volume II is found to be adequate for data collection, based on the required plant metabolism and residue analytical method validation data, no additional storage stability data will be required for plant samples kept frozen for $\leq$ 525 days.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPANIL (cont'd)

§158.125 Residue Chemistry

Footnotes (cont'd)

5/If the required animal metabolism and analytical method validation data indicate that Method II in PAM Volume II is adequate for collection of data regarding residues of propanil in meat and milk, then the cattle feeding study data contained in MRIDs 00035694 and 00035695 must be validated by submission of sample storage information (length of time in storage and conditions of storage) and by data depicting the stability of propanil residues of concern in similar samples under the conditions and for the time intervals specified.

6/Crop group tolerances are not appropriate at the present time because: (1) additional data are required for rice grain; (2) tolerances for residues in the grain and straw of barley, oats, and wheat and in the grain and straw of rice differ by more than a factor of 5; and (3) a lack of data for corn (fresh sweet and dried field) and sorghum, representative commodities of the cereal grains group.

7/The established tolerances for residues in straw are too low. The registrant should propose that they be revised from 0.75 to 1.5 ppm, provided the required plant metabolism and analytical method validation data indicate that the available data for straw are adequate (refer to footnote 2).

8/Data must be submitted depicting residues in bran, flour, middlings, shorts, and grain dust processed or obtained from wheat grain bearing measurable weathered residues. It may be necessary to treat with exaggerated rates to obtain measurable residues in the raw agricultural commodity. If residues concentrate in any of these processed commodities, appropriate food/feed additive tolerances must be proposed.

9/Data must be submitted depicting residues in or on rough rice grain (short season varieties) treated 60 days after planting at 6 lb ai/A and harvested 56 days after treatment. Both ground and aerial applications must be made, in separate tests, according to the label directions. Tests must include the use of both EC and SC/L formulations. Fields must be drained of flood water prior to treatment and reflooded within 24 hours of treatment. Tests must be conducted in Arkansas (38.6%), California (22.1%), Louisiana (16.0%), and Texas (14.7%), which represent > 90% of the U.S. rice production States.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPANIL (cont'd)

§158.125 Residue Chemistry

Footnotes (cont'd)

10/Residues must be determined in the rice grain dust obtained from rough grain bearing measurable weathered residues. If residues are higher in dust than in the rough grain, a feed additive tolerance must be proposed. Also, feed additive tolerance revisions representing a 13X concentration in rice bran and, if necessary (if the tolerance for residues in grain must be revised), a 5X concentration in hulls must be proposed. If the required plant metabolism and analytical method validation data (refer to footnote 2) indicate that the available rice processing studies are adequate, the registrant should propose that the feed additive tolerance for residues in rice bran be revised from 10 ppm to 26 ppm.

11/A metabolism study must be submitted in which crayfish are exposed to [^{14}C-ring]propanil for at least 3 days at a concentration in water sufficiently high to permit complete quantification and characterization of ^{14}C-residues in edible meat. ^{14}C-Balance data must be presented for each sample analyzed. Conjugated or bound ^{14}C-residues must be characterized. Representative samples from this study must be analyzed using current and proposed residue procedures (including FDA multiresidue methods) to ascertain that the methods are capable of accurately quantifying all residues of toxicological concern. This study should be completed and submitted prior to initiation of the crayfish field residue trial required below (footnote 12).

12/Data must be submitted depicting residues in crayfish harvested in early December following treatment of short-season rice fields in Louisiana in mid-July at 6 lb ai/A. The studies may be conducted in conjunction with those required for rice grain. A tolerance for residues in crayfish must be proposed. As an alternative to submitting the crayfish metabolism and residue studies, the following label restrictions may be implemented: "Do not apply to fields where commercial crayfish farming is practiced and do not drain water from treated fields into areas where crayfish farming is practiced."

13/Data must be submitted depicting residues in catfish collected 0, 3, 7, 14, 21, and 28 days after the fish are transferred to a catfish-farming reservoir initially containing 15 ppb propanil residues. A tolerance for residues in catfish must be proposed. Alternatively, the following label restriction may be implemented: "Do not drain water from treated fields into areas where catfish farming is practiced." [The catfish residue trial should not be initiated until the fish bioaccumulation study required under Guideline No. 165-4 has been submitted for evaluation by the Agency.]

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPANIL (cont'd)

§158.125 Residue Chemistry

Footnotes (cont'd)

14/On receipt of all data pertaining to metabolism, analytical methods and feed items, the adequacy of the available cattle feeding study will be determined and specific requirements for a poultry feeding study will be outlined.

15/On receipt of the required data for plant metabolism and analytical method validation, additional data may also be required for the straw and grain of barley, oats, and wheat; the processed products of rice; and rice straw. ALL REQUIRED PLANT METABOLISM AND ANALYTICAL METHOD VALIDATION DATA MUST BE SUBMITTED FOR EVALUATION BY THE AGENCY PRIOR TO INITIATION OF RESIDUE FIELD TRIALS AND PROCESSING STUDIES.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPANIL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.135 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	TGAI	A	No		Yes	9 Months
81-2 - Acute Dermal - Rabbit	TGAI	A	No		Yes	9 Months
81-3 - Acute Inhalation - Rat	TGAI	A	No		Yes	9 Months
81-4 - Eye Irritation - Rabbit	TGAI	A	No		Yes	9 Months
81-5 - Dermal Irritation - Rabbit	TGAI	A	No		Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	TGAI	A	No		Yes	9 Months
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A	No		No[1]/	
Subchronic Testing						
82-1 - 90-Day Feeding						
- Rodent	TGAI	A	Yes	40402901	No	
- Nonrodent	TGAI	A	No		No[2]/	
82-2 - 21-Day Dermal - Rabbit	TGAI	A	No		Yes	12 Months
82-3 - 90-Day Dermal - Rabbit	TGAI	A	No		No[3]/	
82-4 - 90-Day Inhalation - Rat	TGAI	A	No		No[3]/	

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPANIL (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.135 Toxicology						
Subchronic Testing						
82-5 - 90-Day Neurotoxicity						
- Hen	TGAI	A	No		No[4]/	
- Mammal	TGAI	A	No		No[4]/	
Chronic Testing						
83-1 - Chronic Toxicity - Two Species						
- Rodent	TGAI	A	No		Yes	50 Months
- Nonrodent (Dog)	TGAI	A	No		Yes	50 Months
83-2 - Oncogenicity - Two Species						
- Rat (Preferred)	TGAI	A	No		Yes	50 Months
- Mouse (Preferred)	TGAI	A	Partially	00155215	Yes[5]/	50 Months
83-3 - Teratogenicity - Two Species						
- Rat	TGAI	A	Yes	00058588	No	
- Rabbit	TGAI	A	Yes	00058589	No	
83-4 - Reproduction - Rat 2-Generation	TGAI	A	Yes	00036091,00015419	No[6]/	

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPANIL (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.135 Toxicology						
Mutagenicity Testing						
84-2 - Gene Mutation (Ames Test)	TGAI	A	Yes	00155084,00155085, 00152096	No	
84-2 - Structural Chromosomal Aberration	TGAI	A	Yes	00155083	No	
84-4 - Other Genotoxic Effects	TGAI	A	Yes	00155085,00152096	No	
Special Testing						
85-1 - General Metabolism	PAI or PAIRA	A	No		Yes	24 Months

1/Not required since propanil is not expected to elicit a neurotoxic reaction.

2/Not required since a chronic nonrodent study is required.

3/Based on the registered use patterns, this study is not required.

4/This study is not required since the acute neurotoxicity study is not required.

5/It must be demonstrated that the highest dose tested (180 ppm) was the maximum tolerated dose (MTD). NOELs must be established for bilateral retinal degeneration in males and females and thyroiditis in females (for the 85.4% technical). Depending on the outcome of the above issues an additional mouse oncogenicity study may be required.

6/Pending review of the impurity profile of the two registered technicals, this study may need to be repeated.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPANIL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.130 Environmental Fate						
Degradation Studies - Lab						
161-1 - Hydrolysis	TGAI or PAIRA	A,C	Partially	00111395	Yes[1]	9 Months
Photodegradation						
161-2 - In Water	TGAI or PAIRA	A,C	No		Yes	9 Months
161-3 - On Soil	TGAI or PAIRA	A	No		Yes	9 Months
161-4 - In Air	TGAI or PAIRA	A	No		No[2]	
Metabolism Studies - Lab						
162-1 - Aerobic Soil	TGAI or PAIRA	A	No		Yes	27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No		Yes	27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA	C	No		Yes	27 Months
162-4 - Aerobic Aquatic	TGAI or PAIRA	C	No		Yes	27 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPANIL (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.130 Environmental Fate						
Mobility Studies						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,C	Partially	00080125,00143619, 00143620	Yes[3]	12 Months
163-2 - Volatility (Lab)	TEP	A,C	No		No[2]	
163-3 - Volatility (Field)	TEP	A,C	No		No[2]	
Dissipation Studies - Field						
164-1 - Soil	TEP	A	No		Yes	27 Months
164-2 - Aquatic (Sediment)	TEP	C	No		Yes	27 Months
164-3 - Forestry	TEP	--	No		No[4]	
164-5 - Soil, Long-Term	TEP	A,C	No		Reserved[5]	
Accumulation Studies						
165-1 - Rotational Crops (Confined)	PAIRA	A,C	No		Yes	39 Months
165-2 - Rotational Crops (Field)	TEP	A,C	No		Reserved[6]	
165-3 - Irrigated Crops	TEP	C	No		Yes	39 Months
165-4 - In Fish	TGAI or PAIRA	A,C	No		Yes	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPANIL (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.130 Environmental Fate						
Accumulation Studies (cont'd)						
165-5 - In Aquatic Nontarget Organisms	TEP	--	No		Reserved[7]/	
Special Studies						
Ground Water Monitoring	TEP	A	No		Reserved[8]/	

1/Data on the hydrolysis of propanil at pH 5 are required.

2/Not required, based on currently registered use patterns.

3/Data on the mobility of aged propanil are required.

4/Not required because there are no forestry uses for propanil.

5/Reserved pending results of the short-term soil dissipation study. The study will be required if more than half of the applied material remains at the time of the next recommended application.

6/Required if detectable residues are found in the confined rotational crop study.

7/Reserved pending the results of the fish bioaccumulation study.

8/Pending the results of acceptable leaching and soil field dissipation studies, a ground water monitoring study may be required. A ground water monitoring study protocol must be submitted, reviewed, and approved prior to conducting study.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPANIL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.145 Wildlife and Aquatic Organisms						
Avian and Mammalian Testing						
71-1 - Acute Avian Oral Toxicity	TGAI	A,C	No		Yes	9 Months
71-2 - Avian Subacute Dietary Toxicity						
- Upland Game Bird	TGAI	A,C[1]/	Partially[4]/	00088872	Yes	9 months
- Waterfowl	TGAI	A,C	No		Yes	9 Months
71-3 - Wild Mammal Toxicity	TGAI	A,C	N/A[3]/		No	
71-4 - Avian Reproduction						
- Upland Game Bird	TGAI	A,C	No		Reserved[2]/	
- Waterfowl	TGAI	A,C	No		Reserved[2]/	
71-5 - Simulated Field Testing						
- Mammals	TEP	A,C	No		Reserved[2]/	
- Birds	TEP	A,C	No		Reserved[2]/	
- Actual Field Testing						
- Mammals	TEP	A,C	No		Reserved[2]/	
- Birds	TEP	A,C	No		Reserved[2]/	

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPANIL (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.145 Wildlife and Aquatic Organisms Aquatic Organism Testing						
72-1 - Freshwater Fish Toxicity						
- Coldwater Fish Species	TGAI	A,C[1]/	Yes	00084821	No	
- Warmwater Fish Species	TGAI	A,C	Yes	00124276	No	
- Coldwater Fish Species	TEP	C	No		Yes	9 Months
- Warmwater Fish Species	TEP	C	No		Yes	9 Months
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A,C[1]/	Yes	00124277	No	
	TEP	C	No		Yes	9 Months
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TGAI	C	Partially[4]/	00111392 00111391	Yes	12 Months
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life Cycle	TGAI	C	Partially[4]/	00117967	Yes	15 Months
72-5 - Fish Life Cycle	TGAI	C	No		Yes	27 Months
72-6 - Aquatic Organism Accumulation	TGAI	C	No		Reserved[2]/	
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	C	No		Reserved[2]/	

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPANIL (cont'd)

§158.145 Wildlife and Aquatic Organisms

Footnotes

1/Required to support the manufacturing-use product.

2/Reserved pending receipt and review of environmental fate data.

3/Not currently a requirement.

4/Insufficient data submitted with study. Submission of required data may result in fulfillment of this data requirement.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPANIL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.150 Plant Protection						
121-1 - Target Area Phytotoxicity	EP	A,C	N/A[1]/		No	
Nontarget Area Phytotoxicity						
Tier I						
122-1 - Seed Germination/Seedling Emergence	TGAI	A	No		Yes	9 Months
122-1 - Vegetative Vigor	TGAI	A	No		Yes	9 Months
122-2 - Aquatic Plant Growth	TGAI	C	No		Yes	9 Months
Tier II						
123-1 - Seed Germination/Seedling Emergence	TGAI	A	No		Reserved[2]/	
123-1 - Vegetative Vigor	TGAI	A	No		Reserved[2]/	
123-2 - Aquatic Plant Growth	TGAI	C	No		Reserved[2]/	
Tier III						
124-1 - Terrestrial Field	TEP	C	No		Reserved[3]/	
124-2 - Aquatic Field	TEP	C	No		Reserved[3]/	

1/Not currently a requirement.

2/Reserved pending results of Tier I.

3/Reserved pending results of Tier II.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPANIL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.155 Nontarget Insect						
Nontarget Insect Testing - Pollinators						
141-1 - Honey Bee Acute Contact Toxicity	TGAI	A	Yes	00018842	No	
141-2 - Honey Bee - Toxicity of Residues on Foliage	TEP	A	No		No[1]/	
141-4 - Honey Bee Subacute Feeding Study	(Reserved)[2]/					
141-5 - Field Testing for Pollinators	TEP	A	No		No[1]/	
Nontarget Insect Testing - Aquatic Insects						
142-1 - Acute Toxicity to Aquatic Insects	(Reserved)[3]/					
142-1 - Aquatic Insect Life Cycle Study	(Reserved)[3]/					
142-3 - Simulated or Actual Field Testing for Aquatic Insects	(Reserved)[3]/					
143-1 thru 143-3 - Nontarget Insect Testing - Predators and Parasites	(Reserved)[3]/					

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPANIL (cont'd)

§158.155 Nontarget Insect

Footnotes

1/Since data from the acute contact test indicate low toxicity, no further testing is required.

2/Reserved pending development of test methodology.

3/Reserved pending Agency decision as to whether the data requirement should be established.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPANIL

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A	No		No[1]	
132-1 - Soil Dissipation	TEP	A	No		No[1]	
133-3 - Dermal Exposure	TEP	A	No		No[1]	
133-4 - Inhalation Exposure	TEP	A	No		No[1]	

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[1] Based on acute toxicity and use patterns, no data are required at this time.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PROPANIL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?[1]/	Bibliographic Citation[1]/	Must Additional Data Be Submitted?	Timeframe for Submission
§158.120 Product Chemistry						
61-1 - Product Identity and Disclosure of Ingredients	MP	All	No	N/A	Yes[2]/	January, 1988
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All	No	N/A	Yes[3]/	January, 1988
61-3 - Discussion of Formation of Impurities	MP	All	No	N/A	Yes[4]/	January, 1988
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	All	No	N/A	Yes[5]/	12 Months
62-2 - Certification of Limits	MP	All	No	N/A	Yes[6]/	12 Months
62-3 - Analytical Methods to Verify Certified Limit	MP	All	No	N/A	Yes[7]/	12 Months
Physical and Chemical Characteristics						
63-2 - Color	MP	All	No	N/A	Yes[8]/	6 Months
63-3 - Physical State	MP	All	No	N/A	Yes[8]/	6 Months
63-4 - Odor	MP	All	No	N/A	Yes[8]/	6 Months
63-7 - Density, Bulk Density, or Specific Gravity	MP	All	No	N/A	Yes[8]/	6 Months

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PROPANIL (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data Be Submitted?	Timeframe for Submission
§158.120 Product Chemistry						
Physical and Chemical Characteristics (cont'd)						
63-12 - pH	MP	All	No	N/A	Yes[8][9]	6 Months
63-14 - Oxidizing or Reducing Action	MP	All	No	N/A	Yes[8][10]	6 Months
63-15 - Flammability	MP	All	No	N/A	Yes[8][11]	6 Months
63-16 - Explodability	MP	All	No	N/A	Yes[8][12]	6 Months
63-17 - Storage Stability	MP	All	No	N/A	Yes[8]	15 Months
63-18 - Viscosity	MP	All	No	N/A	Yes[8][13]	6 Months
63-19 - Miscibility	MP	All	No	N/A	Yes[8][14]	6 Months
63-20 - Corrosion Characteristics	MP	All	No	N/A	Yes[8]	6 Months
Other Requirements						
64-1 - Submittal of Samples	MP	All	N/A	N/A	No	

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PROPANIL (cont'd)

§158.120 Product Chemistry

Footnotes

1/Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each manufacturing-use product. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/The chemical name and nominal concentration of each impurity for which a certified limit is required must be submitted. In addition, the chemical name, nominal concentration, Chemical Abstracts Service (CAS) Registry Number, and purpose of the active ingredient and each intentionally added inert must be provided. For the active ingredient, the following must also be provided: the product name, trade name, and common name; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned company code numbers.

3/Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions including specification of the available conditions of temperature, pressure and pH, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

4/A detailed discussion of all impurities that are or may be present at $\geq$ 0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted. The discussion must include all details regarding possible formation of dibenzo-p-dioxins and dibenzofurans.

5/Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PROPANIL (cont'd)

§158.120 Product Chemistry

Footnotes (cont'd)

6/Upper and lower limits for the active ingredient and each intentionally added inert, and upper limits for each impurity present at $\geq$ 0.1% (w/w) and each "toxicologically significant" impurity present at $<$ 0.1% (w/w) must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. Limits for impurities not associated with the active ingredient need to be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. Certifications must be submitted on EPA Form 8570, Rev. 2-85.

7/Analytical methods must be provided to determine the active ingredient and each toxicologically significant impurity and intentionally added inert for which certified limits are required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

8/Physicochemical characteristics (color, physical state, odor, specific gravity, pH, oxidizing or reducing action, flammability, explodability, storage stability, viscosity, miscibility, and corrosion characteristics) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D must be submitted.

9/Required if the test substance is dispersible with water.

10/Required if the product contains an oxidizing or reducing agent.

11/Required if the product contains combustible liquids.

12/Required if the product is potentially explosive.

13/Required if the product is a liquid.

14/Required if the product is a liquid and is to be diluted with petroleum solvents.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PROPANIL

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.135 Toxicology						
Acute Testing						
81-1 - Acute Oral Toxicity - Rat	MP	A	No		Yes	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	MP	A	No		Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	MP	A	No		Yes	9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	A	No		Yes	9 Months
81-5 - Primary Dermal Irritation - Rabbit	MP	A	No		Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	A	No		Yes	9 Months

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-7

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

§162.10 Labeling requirements.

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label--(i) General. The label shall appear on or be securely attached to the immediate container of the

pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers--(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) Final printed labeling. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) Name, brand, or trademark. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for ***," "Distributed by ***," or "Sold by ****" to show that the name is not that of the producer.

(d) Net weight or measure of contents. (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68°F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishments registration number. The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) Ingredient statement--(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement. (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) Warnings and precautionary statements. Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) Required front panel statements. With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) Human hazard signal word.--(A) Toxicity Category I. All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) Toxicity Category II. All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) Toxicity Category III. All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) Toxicity Category IV. All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) Use of signal words. Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) Child hazard warning. Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) Statement of practical treatment--(A) Toxicity Category I. A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) Other toxicity categories. The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) Placement and prominence. All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) Other required warnings and precautionary statements. The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) Hazard to humans and domestic animals. (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I . . .	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust] or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II . . .	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.].
III . . .	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV . . .	[No precautionary statements required.].	[No precautionary statements required.].

(ii) Environmental hazards. Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) Physical or chemical hazards. Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20°F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
Flash point above 20°F and not over 80°F or if the flame extension is more than 18 in. long at a distance of 6 in. from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20°F and not over 80°F	Flammable. Keep away from heat and open flame.
Above 80°F and not over 150°F	Do not use or store near heat or open flame.

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(i) Directions for Use--(1) General requirements--(i) Adequacy and clarity of directions. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) Placement of directions for use. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular." and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) Exceptions to requirement for direction for use--(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use*. The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment requried.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of Use Classification. By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification. (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 38571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PEST/DIS-1

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

[1]/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

EPA Compendium of Acceptable Uses

3',4'-DICHLOROPROPIONANILIDE

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Wheat, Spring (hard red)	4

3',4'-DICHLOROPROPIONANILIDE*

TYPE PESTICIDE: Herbicide

FORMULATIONS:
Tech (85%, 90%, 96%)
EC (3 lb/gal or 33% a.i. or 33.1% a.i. or 33.7% a.i. or 33.8% a.i. or 35% a.i. or 35.9% a.i., 4 lb/gal or 43.48% a.i. or 43.5% a.i. or 44.5% a.i. or 45% a.i. or 45.4% a.i.)
SC/L (3 lb/gal or 35% a.i.)

GENERAL WARNINGS AND LIMITATIONS: A contact postemergent herbicide for selective control of grasses and broadleaf weeds in durum wheat, oats, rice fields, spring barley, and spring wheat. Do not tank mix with, or use carbaryl or any organic phosphate insecticide within 14 days before or after treatment. Do not use systemic phosphate insecticides on fields to be treated. Most chlorinated hydrocarbons may be used in separate sprays or as seed treatments. Tank mix sprays may cause some temporary tip burn to crops. Do not add oils, adjuvants, or liquid fertilizers. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.
Environmental Hazards: This pesticide is toxic to fish. Do not apply when weather conditions favor drift from treated areas. Do not apply directly to water except as specified on labeling or, for nonaquatic use, in wetlands (swamps, bogs, marshes and potholes). Do not contaminate water by cleaning of equipment or disposal of wastes.
Livestock Tolerances:

Cattle, fat	0.1	(N) ppm
Cattle, meat	0.1	(N) ppm
Cattle, mbyp	0.1	(N) ppm
Eggs	0.05	(N) ppm
Goats, fat	0.1	(N) ppm
Goats, meat	0.1	(N) ppm
Goats, mbyp	0.1	(N) ppm
Hogs, fat	0.1	(N) ppm
Hogs, meat	0.1	(N) ppm
Hogs, mbyp	0.1	(N) ppm
Horses, fat	0.1	(N) ppm
Horses, meat	0.1	(N) ppm
Horses, mbyp	0.1	(N) ppm
Milk	0.05	(N) ppm
Poultry, fat	0.1	(N) ppm
Poultry, meat	0.1	(N) ppm
Poultry, mbyp	0.1	(N) ppm
Sheep, fat	0.1	(N) ppm
Sheep, meat	0.1	(N) ppm
Sheep, mbyp	0.1	(N) ppm

TIME REQUIRED FOR CONTROL: Three to 5 days.

PHYTOTOXICITY TO TARGET WEEDS: Causes chlorosis followed by necrosis of leaves of susceptible plants.

*Propanil

3',4'-DICHLOROPROPIONANILIDE

PHYTOTOXICITY TO CROPS: Under some conditions, yellowing or tip burning is visible.

MODE OF ACTION: Inhibits a number of biochemical reactions, especially photosynthesis.

BROADLEAF WEEDS CONTROLLED:

PAAAAAC	Broadleaf weeds
PCQATBA	Coffeeweed
PCBABBA	Common St. Johnswort
PBVAEAA	Croton
PEAAHBE	Curly dock
PCQBSBB	Hemp sesbania
PCQCBAA	Indigo
PBDAIBA	Kochia
PBDAEAB	Lambsquarter
PBVACBA	Mexicanweed
PCQADBB	Northern jointvetch
PAFACBC	Prostrate pigweed
PAFACBI	Redroot pigweed
PEYABBA	Redweed
PEAAHAB	Sour dock
PBFBVBB	Spikeweed
PCADSBA	Texasweed
PBVAEBA	Woolly croton
PEAAGBH	Wild buckwheat
PBKBKBB	Wild mustard

GRASSES AND OTHER MONOCOTS CONTROLLED:

PZAAAAO	Baronetgrass	
PCABHBB	Barnyardgrass	
PZAAAAP	Bashfulweed	
PCAAHAA	Bluestem	
PCABFAA	Crabgrass	
PCABIBA	Goosegrass	
PCAAAAA	Grasses	
PCACUBF	Green foxtail	
PCABHBD	Gulf cockspur	
PBMAHBA	Horned beakrush	
PCACFBJ	Hurrahgrass	
PCACWBC	Johnsongrass	(a)
PBMADBC	Jointed flatsedge	
PCABHBA	Junglerice	
PCACFBD	Knotgrass	(a)
PCACFBK	Longtom	(a)
PCAAAAI	Millet	
PBMADAA	Nutsedge	
PCAARBB	Paragrass	
PCAAHAA	Plains bluestem	
PBMADBM	Purple nutsedge	

GRASSES AND OTHER MONOCOTS CONTROLLED (continued)

PBMABAA	Sedge
PCAARAA	Signalgrass
PBMAEAA	Spikerush
PCACEBL	Texas millet
PCACEBL	Texas panicum
PAAAABC	Wiregrass
PCACUBF	Yellow foxtail

(a) Partial control. Weeds temporarily injured but usually recover.

AQUATIC WEEDS CONTROLLED:

PAFABBA	Aligatorweed	
PAAAAAN	Aquatic weeds	(a)
PAEADAA	Arrowhead	(a)
PBMAGAA	Bulrush	(a)
PFDABAA	Cattail	(a)
PECACBB	Ducksalad	(a)
PCYABBA	Redstem	(a)
PAEABAA	Waterplantain	(a)

(a) Partial control. Weeds temporarily injured but usually recover.

3',4'-DICHLOROPROPIONANILIDE

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	TERRESTRIAL FOOD CROP	
	(Agricultural Crops)	
/24001AA /24003AA /24007AA	Barley, Spring Oats Wheat, Durum	0.2 ppm (barley, grain) (oats, grain) (wheat, MCPA, isooctyl ester.
	[MAI] ** (3 lb/gal EC)	Label data incomplete. Formulated with MCPA, isooctyl ester.
/24007AA	Wheat, Spring (hard red)	0.2 ppm (wheat, grain) 0.75 ppm (wheat, straw) General Information: Do not apply to spring wheat beyond the 5-leaf stage. Do not spray within 600 feet of any permanent body of water. Do not spray under windy conditions or allow spray to drift to adjacent susceptible crops. Do not apply if frost is expected within 24 hours or when temperatures are above 85 F (29.4 C).
	1.13-1.50 (3 lb/gal EC)	Postemergence. Broadcast. Apply in 15 to 20 gallons of water per acre by ground or 5 to 10 gallons of water per acre by air when weeds are in the 2- to 4-leaf stage. Use the higher dosage when weeds are in the 4- to 6-leaf stage. Make 1 application per growing season. May be tank mixed with MCPA, isooctyl ester.
	[MAI] ** (3 lb/gal EC)	Label data incomplete. Formulated with MCPA, isooctyl ester.

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	Wheat, Spring (hard red) (continued)	
	[SLN] 1.12-1.50 (3 lb/gal EC)	SLN - Use limited to ND. Postemergence. Broadcast. For control of green foxtail, yellow foxtail, and broadleaf weeds. Apply in 10 gallons of water per acre by air. Use the lower dosage when foxtails are in the 2- to 3-leaf stage and broadleaf weeds are in the 2- to 4-leaf stage and actively growing. Use the higher dosage when foxtails are in the 3 to 4-leaf stage.
	AQUATIC FOOD CROP	
	(Agricultural Crops)	
/24004AA	Rice	2 ppm (rice) 10 ppm (rice bran, hulls, polishings, milled fractions) 75 ppm (rice, straw) 56 day preharvest interval. To avoid residues at harvest, do not apply after mid-tillering stage or later than 60 days after planting rice. Do not exceed a total of 9 pounds active ingredient per acre per season. Do not apply to second rice crop when double cropping is practiced. Water drained from treated rice fields must not be used to irrigate other crops or released within one-half mile upstream of a potable water intake in flowing water (i.e., river, stream, etc.) or within one-half mile of a potable water intake in a standing body of water such as a lake, pond or reservoir. General Information: Seedbeds should be well worked and free of large clods to encourage uniform and rapid germination of rice, grass, and weeds, and to ensure uniform flood levels. To prevent more weeds from germinating after treatment, fields should be flooded within 24 hours of spraying. Apply to fields which have been drained of flood water. If the rice is too small to maintain a flood on the field, treatment should be delayed until the rice is larger. Avoid treatment if

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
Rice (continued)	
4-6 (3, 4 lb/gal EC)	Use limited to CA. Postemergence. Broadcast. For control of barnyardgrass. Use where rice fields are not completely drained. Apply 30 to 45 days after planting, before rice is fully tillered, when barnyardgrass extends 6 to 8 inches above the water surface. If rice has been deep flooded, water levels may be lowered. Use 4 pounds active ingredient per acre if grass has 3 to 5 leaves, 5 pounds active ingredient per acre if 5 to 6 leaves, and 6 pounds active ingredient per acre if 7 or more leaves are present. Apply in no less than 10 to 12 gallons of water per acre using a medium-fine spray. If a high water level is desired after treatment, reflooding may start 12 hours after treatment.
[MAI] 2.2-3.0 (3 lb/gal EC)	Use limited to southern United States. Postemergence. Broadcast. Apply in 20 to 50 gallons of water per acre by ground or in 10 to 15 gallons of water per acre by air. Use the lower dosage when rice is in the 1- to 2-leaf stage and the higher dosage when rice is in the 3- to 4- leaf stage. Flood rice fields within 5 days after treatment. Do not apply through irrigation systems. Formulated with S-ethyl hexahydro-1H-azepine-1-carbothioate.
[MAI] 2.2-3.0 (3 lb/gal EC)	Postemergence. Broadcast. Apply in 15 to 25 gallons of water per acre by ground or in 10 to 12 gallons of water per acre by air. Use the lower dosage on coarse sandy loams and when rice is in the 1- to 3-leaf stage, and the higher dosage on medium or fine clay loams. Do not apply in liquid fertilizer. Do not make more than 1 application per season. Do not bale or use rice straw for feeding or bedding. Formulated with pendimethalin.

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
Rice (continued)	
4-6 (3, 4 lb/gal EC)	Use limited to CA. Postemergence. Broadcast. For control of barnyardgrass. Use where rice fields are not completely drained. Apply 30 to 45 days after planting, before rice is fully tillered, when barnyardgrass extends 6 to 8 inches above the water surface. If rice has been deep flooded, water levels may be lowered. Use 4 pounds active ingredient per acre if grass has 3 to 5 leaves, 5 pounds active ingredient per acre if 5 to 6 leaves, and 6 pounds active ingredient per acre if 7 or more leaves are present. Apply in no less than 10 to 12 gallons of water per acre using a medium-fine spray. If a high water level is desired after treatment, reflooding may start 12 hours after treatment.
[MAI] 2.2-3.0 (3 lb/gal EC)	Use limited to southern United States. Postemergence. Broadcast. Apply in 20 to 50 gallons of water per acre by ground or in 10 to 15 gallons of water per acre by air. Use the lower dosage when rice is in the 1- to 2-leaf stage and the higher dosage when rice is in the 3- to 4- leaf stage. Flood rice fields within 5 days after treatment. Do not apply through irrigation systems. Formulated with S-ethyl hexahydro-1H-azepine-1-carbothioate.
[MAI] 2.2-3.0 (3 lb/gal EC)	Postemergence. Broadcast. Apply in 15 to 25 gallons of water per acre by ground or in 10 to 12 gallons of water per acre by air. Use the lower dosage on coarse sandy loams and when rice is in the 1- to 3-leaf stage, and the higher dosage on medium or fine clay loams. Do not apply in liquid fertilizer. Do not make more than 1 application per season. Do not bale or use rice straw for feeding or bedding. Formulated with pendimethalin.

Site, Dosage and Formulation (lb a.i./A)		Tolerance, Use, Limitations
	AERIAL AND TANK MIX APPLICATIONS	
9001500 AAAAAAA	Aerial Application	
	--	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) Barley, Spring; Oats; Wheat, Durum; Wheat, Spring AQUATIC FOOD CROP (Agricultural Crops) Rice
9900300 AAAAAAA	Tank Mix	
	--	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) Barley, Spring; Oats; Wheat, Durum

3',4'-DICHLOROPROPIONANILIDE

Listing of Registered Pesticide Products by Formulation

&085.0001 85% technical chemical
3',4'-dichloropropionanilide (028201)
000707-00108

&090.0001 90% technical chemical
3',4'-dichloropropionanilide (028201)
056077-00033

&096.0001 96% technical chemical
3',4'-dichloropropionanilide (028201)
000707-00181

&233.0012 33% (3 lb/gal) emulsifiable concentrate
3',4'-dichloropropionanilide (028201) plus 2-methyl-4-chlorophenoxyacetic acid, isooctyl ester (030563)
000707-00182*
*incomplete label

&233.1012 33.1% (3 lb/gal) emulsifiable concentrate
3',4'-dichloropropionanilide (028201) plus S-ethyl hexahydro-1H-azepine-1-carbothioate (041402)
000476-02236

&233.7012 33.7% (3 lb/gal) emulsifiable concentrate
3',4'-dichloropropionanilide (028201) plus N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine (108501)
038167-00010

&233.8012 33.8% (3 lb/gal) emulsifiable concentrate
3',4'-dichloropropionanilide (028201)
000707-00075

(000707-00075) ND800011

&235.0012 35% (3 lb/gal) emulsifiable concentrate
3',4'-dichloropropionanilide (028201)
000707-00094 000707-00110 001439-00229# 048957-00010
056077-00035
#extracted from fiche

&235.9012 35.9% (3 lb/gal) emulsifiable concentrate
3',4'-dichloropropionanilide (028201)
019713-00030

&243.4812 43.48% (4 lb/gal) emulsifiable concentrate
3',4'-dichloropropionanilide (028201)
005905-00182 056077-00034

&243.5012 43.5% (4 lb/gal) emulsifiable concentrate
3',4'-dichloropropionanilide (028201)
000707-00109

Listing of Registered Pesticide Products by Formulation (continued)

&244.5012 44.5% (4 lb/gal) emulsifiable concentrate
3',4'-dichloropropionanilide (028201)
000707-00112

&245.0012 45% (4 lb/gal) emulsifiable concentrate
3',4'-dichloropropionanilide (028201)
005905-00077 009779-00272 019713-00031 048957-00008

&245.4012 45.4% (4 lb/gal) emulsifiable concentrate
3',4'-dichloropropionanilide (028201)
046193-00008

&235.0015 35% (3 lb/gal) soluble concentrate/liquid
3',4'-dichloropropionanilide (028201)
005905-00068 013166-00014 042545-00046 049857-00009

Appendix A-1

Listing of Active Ingredient(s) Found in Combination with the Report Chemical

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
041402	S-ethyl hexahydro-1H-azepine-1-carbothioate	--
030563	MCPA, isooctyl ester	2-methyl-4-chlorophenoxyacetic acid, isooctyl ester
108501	pendimethalin (ANSI)	N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine

-- Use Common Name

Appendix A-2

Listing of Active Ingredient(s) Which May Be Included in Tank Mixes

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
030563	MCPA, isooctyl ester	2-methyl-4-chlorophenoxyacetic acid, isooctyl ester

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

BIBGUIDE-2

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
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00018842	Atkins, E.L., Jr.; Anderson, L.D.; Greywood, E.A. (1969) Effect of Pesticides on Apiculture: Project No. 1499; Research Report CF-7501. (Unpublished study received May 8, 1971 under 1F1174; prepared by Univ. of California--Riverside, Dept. of Entomology, submitted by Ciba Agrochemical Co., Summit, N.J.; CDL:090973-B)
00035576	Monsanto Company (1969) Summary of Residue Findings: Rogue. (Unpublished study received Sep 18, 1971 under 1F1036; CDL:091920-A)
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00035687	Mueller, K.E.; Cherry, W.F.; Smith, L.G.; et al. (1966) Stam Residues on Rough Rice. (Unpublished study including Research Report No. 57-24; received Jun 11, 1970 under 0F0932; prepared in cooperation with Univ. of Arkansas, Agricultural Extension Service, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL: 091588-F)
00035688	Cherry, W.F.; Johnson, W.H.; Owens, F.C.; et al. (1967) Residues of Stam F-34 on Rice. (Unpublished study received Jun 11, 1970 under 0F0932; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:091589-A)
00035692	Johnson, W.H.; Hendrick, R. (1965) Crayfish from Rice Fields Residue Data. (Unpublished study received Jun 11, 1970 under 0F0932; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL: 091589-E)
00035694	Gordon, C.F. (1967) A Study To Determine Residue Levels in Milk and Tissues from Cows Fed Stam Residues as Found in Rice Bran and Straw: 23-5. (Unpublished study received Jun 11, 1970 under 0F0932; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL: 091589-G)
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00035697	Gordon, C.F.; Haines, L.D. (1967) A Study To Determine Residue Levels in Eggs and Tissues from Chickens Fed either C14-Labeled Stam or Stam Residues as Found in Rice Straw. (Unpublished study received Jun 11, 1970 under 0F0932; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:091589-J)

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OFFICE OF PESTICIDE PROGRAMS
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00055546	Rohm and Haas Company (1979) Efficacy of Stampede on Cereal Grains and Various Crops. (Unpublished study received Oct 21, 1980 under 707-75; CDL:243518-A)
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40402901	McLaughlin, J. (1983) Stam: A Three Month Dietary Study in Mice. Report Number 82R-0065. Unpublished report prepared by Toxicology Department, Rohm and Haas Company. 182 p.

OMB Approval No. 2000-0468

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.________________________ Date ________________________________

Registration Standard for ____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	(For EPA Use Only) MRID Numbers Assigned
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) MRID Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ____________

Registrant's Name and Address: ______________________________

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated __________ concerning a requirement for submission of generic data on the active ingredient __________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula(CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated ________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ______________ and their registration number(s) is/are __________ .

(4) My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product to one that is not registered and purchased.

(5) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(6) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: ______________________________
(Signature)

Dated: ______________ ______________________________
(Typed)

EPA Form 8570-27